

# ExAblate<sup>2000</sup>

MR  
guided **Focused Ultrasound Surgery**



*A patient's guide  
to a non-invasive surgery treatment  
for uterine fibroids*

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***InSightec.***   
*Bringing therapy into focus*

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## **User Assistance**

For further information on the ExAblate device please contact InSightec.

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## Glossary

<b>Abdomen/Abdominal</b>	The area of the body between the chest and the pelvis/Located in the area of the abdomen.
<b>Ablate</b>	To destroy (kill) tissue (see <i>Thermal Ablation</i> below).
<b>Acoustic Energy</b>	Another term for "Sound" energy.
<b>Contrast Agents</b>	Substance injected into blood stream that highlights blood flow in MR images.
<b>Coupling pad</b>	A gel pad that helps transfer of the acoustic wave from ExAblate transducer to body without distortion.
<b>Focused Ultrasound Transducer</b>	A device that converts an electrical signal to <i>ultrasound</i> waves and focuses the <i>ultrasound</i> waves.
<b>Hormones</b>	Chemicals secreted by the body and carried by the blood stream to a tissue that the chemicals affect..
<b>MRgFUS</b>	MR guided Focused <i>Ultrasound</i> Surgery.
<b>Magnetic Resonance Imaging (MRI)/MR Images</b>	A non-invasive imaging method using magnetic fields and radio waves to create images (pictures) of the body/The images created.
<b>Menopause</b>	The time in a woman's life when her menstrual cycle stops.
<b>Implants</b>	Devices surgically placed inside the body – including, but not limited to, surgical clips, pacemakers, artificial hips and joints, certain replacement heart valves.
<b>ExAblate Treatment</b>	A procedure in which <i>uterine fibroids</i> are heated and destroyed ( <i>ablated</i> ) using high frequency, high energy sound waves. The procedure is performed inside a <i>MRI</i> device that allows the physician to use the images to plan, monitor and control the <i>treatment</i> while it is in progress.
<b>Patient Table</b>	The part of the ExAblate device that the patient lies on during the <i>treatment</i> .
<b>Scanning</b>	A term used to describe the process of acquiring the <i>MR image</i> .
<b>Sonication</b>	A sonication refers to a single exposure of focused <i>ultrasound</i> .
<b>Temperature Sensitive Images</b>	<i>MRI</i> generated images that show both structures inside the body and temperature. These are used during the <i>sonications</i> of the <i>ExAblate treatment</i> to determine if the fibroid has been sufficiently heated.
<b>Thermal Ablation</b>	To destroy (kill) tissue by the direct application of heat.
<b>Treating/Treatment</b>	A term used to describe the part of the procedure that is the total time during which the fibroid(s) is(are) being ablated.
<b>Ulceration</b>	Loss of tissue (e.g., skin or mucous) due to inflammation.
<b>Ultrasound</b>	High frequency sound waves (not audible to the human ear).

- Uterine Fibroids** Non-cancerous (benign) masses located in the uterus or in the uterine wall.
- Workstation** The part of the ExAblate device that the physician uses to plan, control and monitor the *treatment*.

Note: *Italicized* words are defined in the glossary on page 3.

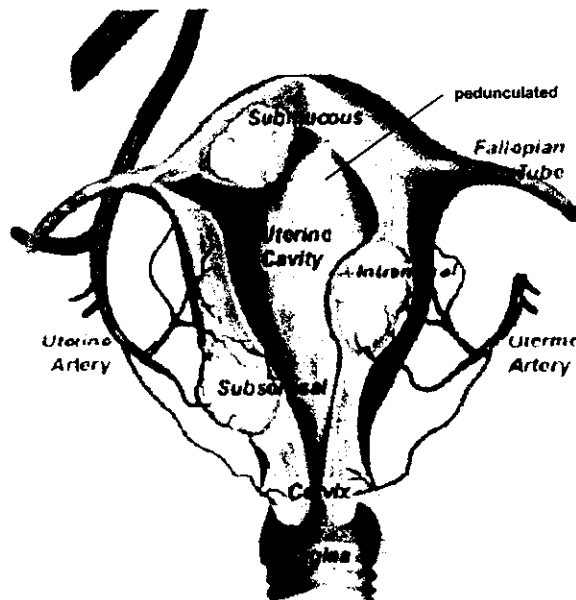
### **What are uterine fibroids?**

*Uterine fibroids* (also referred to as myomas, leiomyomas, leiomyomata, and fibromyomas) are non-cancerous (benign) tumors that grow within the muscle tissue of the uterus. Approximately 20-40% of women 35 years and older have fibroids. While many women with fibroids do not experience any symptoms, the location and size of fibroids can cause symptoms that can affect a woman's quality of life.

Fibroids are hormonally sensitive so symptoms are likely to be cyclical with menstruation. Fibroid growth is dependent on *hormone* levels; an increase in a woman's *hormone* levels may cause the size of fibroids to increase. During *menopause*, these *hormones* decrease dramatically and may cause fibroid symptoms to diminish.

The size of a fibroid can be very small (dime sized), the size of a cantaloupe, or even larger. There can either be one dominant fibroid, a cluster of many small fibroids, or a combination.

Fibroids are also classified according to their location. There are four primary types of fibroids, although many fibroids cannot be purely classified into one of these categories:



<b><i>Subserosal fibroids</i></b>	These fibroids develop in the outer portion of the uterus and continue to grow outward.
<b><i>Intramural fibroids</i></b>	The most common type of fibroid. These develop within the uterine wall.
<b><i>Submucosal fibroids</i></b>	These fibroids develop just under the lining of the uterine cavity.
<b><i>Pedunculated Fibroids</i></b>	Fibroids that grow on a small stalk that connects them to the inner or outer wall of the uterus.

### ***What are common symptoms of fibroids?***

- Very heavy and prolonged monthly periods, sometimes with clots
- Pain in the back or in the legs
- Pelvic pain or pressure
- Pain during sexual intercourse
- Pressure on the bladder which leads to a constant need to urinate, incontinence, or the inability to empty the bladder
- Pressure on the bowel which can lead to constipation and/or bloating
- An enlarged *abdomen* which may be mistaken for weight gain or pregnancy

### ***How do I know I have fibroids?***

During your annual well-woman examination, or if you schedule a special visit to investigate symptoms similar to those described in the previous section, your doctor will check your uterus. If it feels enlarged, your doctor may order an *abdominal* or transvaginal *ultrasound* or a *magnetic resonance imaging (MRI)* exam of your pelvis, which can confirm the presence, location, and size of fibroids. After identifying the size and location of your fibroids, and possibly after other diagnostic tests, your doctor may be able to rule out other conditions, advise you of options, and provide a recommendation for treatment.

### ***What are my treatment alternatives?***

Currently, the following treatment alternatives are available:

- Watchful waiting
- Hysterectomy
- *Abdominal* myomectomy
- Laparoscopic or hysteroscopic myomectomy
- Uterine artery embolization
- Hormone therapy
- ExAblate MR guided Focused *Ultrasound* Surgery

You should have a detailed discussion with your doctor that includes the chance of success and possible side effects of any treatment option that you choose. Only you and your doctor can decide which choice is best for you. It is important that you are well informed of all of the options that are available to you.

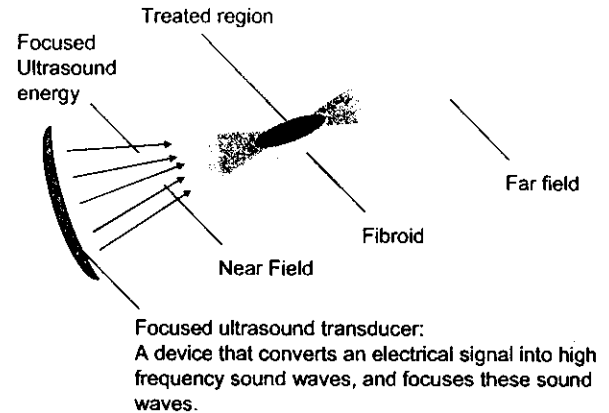
### ***What does ExAblate treatment involve?***

ExAblate can be used for submucosal, subserosal, and intramural *uterine fibroids*. More than one fibroid can be treated. Fibroids which are pedunculated (hanging from a stalk), close to sensitive organs (such as bowel or bladder), or in a location inaccessible by the focused *ultrasound*, may be untreatable. Your physician will determine if your fibroids are suitable for *treatment* with ExAblate.

*Focused ultrasound* surgery involves using *ultrasound* energy to heat a small volume of tissue inside the body to the point of *thermal ablation* (the heating of tissue to a high enough temperature to kill the cells). Similar to the way a magnifying glass focuses light;

during a single activation of energy, called a 'sonication', *ultrasound* waves are directed through your abdomen and *ablate* a small volume of tissue, approximately the size of a jellybean. The *treatment* is guided by *temperature sensitive images* created using *magnetic resonance imaging*. These images allow temperature changes inside the body to be observed during *treatment*. The combination of *focused ultrasound* and *magnetic resonance imaging* allows the physician to perform the procedure without surgical incision. During the *treatment*, the doctor will first obtain *MR images* of your uterus and use these images to plan your *treatment*. Then, individual *sonications* will destroy pieces of your fibroid until the doctor is satisfied with the amount of fibroid that has been treated. The number of *sonications* can range from 40 to 100 and each one takes just under 2 minutes. The entire *treatment* may take up to 3 to 4 hours. After all the *sonications* are completed, *MR images* will again be taken to evaluate how effective the *treatment* has been.

The ExAblate treatment uses *ultrasound* energy to heat the fibroid to the point of thermal ablation (the heating of tissue to a temperature resulting in the killing of the cells). Similar to the way a magnifying glass focuses light; ultrasound waves are directed through the patient's abdomen and into the fibroid.



#### ***What kind of patients cannot be treated with ExAblate?***

Patients who cannot have MRI cannot be treated with ExAblate. This includes all patients with metallic *implants* as well as patients who cannot fit into the MR scanner.

#### ***What if I want to be pregnant after my treatment?***

**ExAblate treatment is not intended for women who desire future pregnancy.** The effects of ExAblate on the ability to become pregnant and carry a fetus to term, and on the development of the fetus, have not been determined. The procedure may alter the composition and integrity of the uterine tissue. You may be at increased risk for complications such as preterm delivery, cesarean delivery, post-delivery bleeding and tearing of the uterus. If you should become pregnant following *ExAblate treatment* you should immediately contact your doctor.

#### ***What are the benefits?***

- An alternative to invasive surgery or hormonal treatment
- No incision required
- The uterus and cervix are not removed
- No hospital stay
- Quick return to normal activities
- With a successful *treatment*, a significant improvement in your quality of life
- Decrease in menstrual bleeding from symptomatic fibroids
- Decrease in urinary dysfunction, pelvic pain and/or pressure

***What are the risks and complications associated with ExAblate treatment?***

The complications that have been reported are listed below. You should talk to your doctor about these short term and long term complications.

**Short term** (those which normally resolve within 10-14 days of the *treatment*)

- Low blood pressure or fainting during or after procedure
- *Abdominal* pain/cramping
- Nausea
- Fever
- Allergic reaction to contrast media or medications
- Minor skin injury (burns)
- Back or leg pain that persists for a few days
- Urinary tract infection

**Long term** (those lasting longer than 14 days after the *treatment*)

- *Abdominal* skin burn with *ulceration*
- Back or leg pain or weakness from nerve damage that may persist for a long period of time, or may be permanent

**Potential risks**

- Although it was not seen in previous clinical trials, there are the potential risks of gynecological infection, damage to organs adjacent to the uterus, blood clots, and death from this *treatment*.

**Outcome Risks with ExAblate**

- There is a risk that the *treatment* may not be successful and you may require one of the other treatments to improve your symptoms.
- The *treatment* may be successful in reducing the symptoms from the fibroids that are treated, but at a later time, fibroids may grow and become symptomatic requiring additional *treatment*. In the clinical trial, 21% of the subjects had another surgical treatment for fibroids within 1 year.

If you have any questions concerning risks and complications of the procedure, you should discuss them with your doctor.

***What information should I share with my doctor before treatment begins?***

Before you undergo *ExAblate treatment* you should discuss:

- Your personal health history, including any allergies you may have
- Your family's health history
- Any recent illnesses
- Medicines, include both prescription, over-the-counter and herbal medicines or dietary supplements



- Any *implants* and/or medical patches
- Recent activities, including air travel
- Your level of normal physical activity
- Previous MR or CT imaging studies

***What should I do to prepare for the procedure***

You will be asked to refrain from eating or drinking for at least six hours prior to the *treatment*. However, you may be allowed to take routine prescribed medication with a little water. You should not take aspirin, ibuprofen, or Motrin for seven days prior to the *treatment*.

You will be asked to shave your abdomen the night prior to the procedure. This is necessary to ensure proper acoustic coupling – i.e., to ensure that the *focused ultrasound* beam can travel from the device to your fibroid without being reflected or distorted at the skin surface due to pubic hair. To further ensure acoustic coupling, do not apply talcum powder, cream, or oil to your abdomen before the procedure. You will also be asked to point out any *abdominal* scars to the treating physician as scar tissue absorbs more *ultrasound* energy than normal skin.

***What should I know before the procedure?***

You should let your doctor know if you have any of the following: allergies to any medication or *contrast agents*, metallic *implants*, or medical patches. Your doctor needs to know so that he can avoid any type of reaction during the procedure.

Your doctor will use conscious sedation, which means you will be awake during the *procedure* but you may feel groggy. You will be able to communicate with your doctor throughout the entire procedure. This communication is important to help prevent injuries (e.g., nerve injuries).

***Is this treatment appropriate for me if I am claustrophobic?***

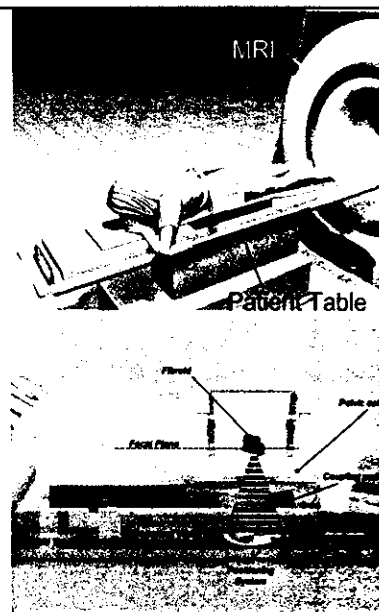
Claustrophobia is the fear of small or enclosed spaces. During the *ExAblate treatment*, you will lie on the *patient table* inside the *MRI scanner* for 3-4 hours. This is a long, narrow tube that does not allow much room between the patient and the sides of the scanner. You will have some medication to help you relax. If you think you may become uncomfortable in small or enclosed spaces, you should discuss this with your doctor.



### ***What will I experience during the treatment?***

- You will lie on the *patient table*. The doctor will give you some medication to help you relax and make sure you are comfortable before starting *treatment*.
- You will remain awake and must be able to communicate with your doctor during the entire *treatment*.
- You will be positioned in a MR scanner and the clinical team will be in the room next to you.
- You will be able to have two-way communication with the doctor using a microphone and a speaker.
- The doctor will inform you when images are being acquired (*scanning*) and when the ExAblate is sonicating (*treatment*).
- During MR *scanning*, you will hear a series of loud noises. Ear protection will be provided.
- During the procedure you will be required to lie still on the *patient table* for a period of 3-4 hours inside the *MRI* scanner.
- During *treatment*, you may feel a warming sensation in the pelvic region. However, you will be given a safety stop button that allows you to immediately stop the *sonication* if it becomes painful.

You will lie on the ExAblate patient table which fits in a standard MR scanner. On the patient table is a transducer. This is a device that generates focused ultrasound directed at the fibroid. A coupling pad conducts the acoustic waves into the body. An MR pelvic coil will be placed over you. This pelvic coil is part of the MR scanner that acquires images of the inside of your body.



### ***What happens to me after the procedure?***

The *ExAblate treatment* is performed as an outpatient procedure that takes 3-4 hours. Following the *treatment*, you will rest for an additional 1-2 hours. You may experience some degree of *abdominal* pain, cramping and nausea shortly after the procedure. Your doctor will decide what medications you may need if this happens. You will need someone to drive you home.

### ***What happens when I go home?***

Based on how you are feeling, you will receive discharge instructions from your doctor regarding medications you may need to keep you comfortable. Usually, over-the-counter pain relief medication is all that is required. You may experience some cramping, similar to menstrual period cramping, or shoulder or back pain from lying in the *treatment* position.

Most women are able to return to work within 1-2 days.

### ***Need to Adhere to Care Regimen***

If you experience any of the following complications, or have any concerns post-procedure, contact your physician immediately.

- Low blood pressure or feeling light headed
- *Abdominal* pain/cramping
- Nausea
- Fever
- Allergic reaction to contrast media or medications
- Minor skin injury, reddening or blistering
- Back or leg pain that persists for a few days
- *Abdominal* skin burn with *ulceration*
- Back or leg pain or weakness that may persist for a long period of time, or may be permanent
- Shortness of breath
- Symptoms of urinary burning or urgency

### ***Who will provide my post procedure care?***

It is important that you and your doctor discuss who will handle your follow-up care, phone calls and/or office visits after the procedure. You should also know who to contact in case of an emergency after your procedure. This is especially important if you are experiencing fever, pelvic pain, or foul-smelling vaginal discharge after the procedure that increases over time and lasts more than 24 hours.

### ***How soon after the *treatment* will my symptoms be gone?***

Most patients find relief in their fibroid related symptoms within the first 3 months. In a previous clinical study conducted by InSightec, 109 women who had symptomatic *uterine fibroids* were treated with the ExAblate at 7 medical centers around the world. After 6 months, 70.6% percent of women had experienced an improvement in their symptoms. Of the women who continued in the study at the 12 month time point, 50.4% continued to experience an improvement in their symptoms.

The *treatment* may be successful in reducing the symptoms from the fibroids that are treated. You may have more fibroid growth over time leading to symptoms that require additional *treatment* in the future. This is true for all fibroid treatments, except hysterectomy. In the clinical trial, 21% of the women had alternative surgical treatment for their fibroids symptoms within 1 year.

### ***Can I get more information about ExAblate?***

More information on the ExAblate device can found by visiting [www.insightec.com](http://www.insightec.com). If you decide to undergo this *treatment*, you should discuss the procedure and any possible complications you might experience with your doctor.